UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

JAMES CARRIGAN, a consumer residing in Washington, individually and on behalf of all others similarly situated, Plaintiff, v. JOHNSON & JOHNSON, a New Jersey corporation; THE PROCTER & GAMBLE COMPANY, an Ohio corporation; and WALGREEN CO., an Illinois corporation, Defendants.	Case No.: 2:23-cv-1481 **CLASS ACTION ALLEGATION COMPLAINT** Unlawful Trade Practices (28 U.S.C. § 1332) DEMAND FOR JURY TRIAL

Plaintiff JAMES CARRIGAN ("Plaintiff"), individually and on behalf of all others similarly situated, make the following allegations based on personal knowledge, and otherwise, upon information and belief:

NATURE OF THE ACTION

1. This case centers around Defendants' over-the counter drugs containing phenylephrine ("PE"). Such products include the following manufactured, marketed, distributed, and/or sold by Defendants JOHNSON & JOHNSON ("J&J"), THE PROCTER & GAMBLE COMPANY ("P&G"), and WALGREEN CO. ("Walgreens"):

- Severe Cold & Flu (Walgreens);
- Severe Sinus (Walgreens);
- Severe Sinus Congestion (Walgreens);
- Sinus Pressure & Pain (Walgreens);
- Tylenol Cold + Flu (J&J);
- Tylenol Cold Multi-Symptom (J&J);

- Tylenol Cough and Cold (J&J);
- Tylenol Sinus (J&J);
- Vicks DayQuil (P&G);
- Vicks NyQuil (P&G);
- Vicks QlearQuil (P&G); and
- Wal-Phed PE (Walgreens).

Collectively, these products and Defendants' other PE products are referred to herein as the "PE Drugs."

2. Defendants' PE Drugs are marketed by each Defendant as effective for treating indications identified on the label, most often nasal congestion.

3. On September 12, 2023, an FDA advisory panel unanimously voted 16-0 that PE is *not* effective for treating nasal congestion.[1] As stated by the panel, PE is "not effective as a nasal decongestant." Thus, it recommends avoiding unnecessary costs or delays in care by "taking a drug that has no benefit."[2]

4. At all relevant times, Defendants represented that their PE Drugs were properly branded and effective for treating the indications identified, including, *inter alia*, treating nasal congestion.

5. These representations were false, as Defendants' PE Drugs were not effective for treating all the indications identified and/or were misbranded.

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[1] C. Jewett, A Decongestant in Cold Medicines Doesn't Work at All, an F.D.A. Panel Says, NEW YORK TIMES, https://www.nytimes.com/2023/09/12/health/cold-medicine-decongestant-fda.html? (last accessed Sept. 17, 2023).

[2] *Id.*

6. Further, each Defendant willfully ignored scientific and industry knowledge concerning the lack of effectiveness of PE Drugs for treating the indications identified, and performed inadequate testing and quality oversight of their respective PE Drugs to ascertain properly the true efficacy of their PE Drugs for treating the indications identified (principally, nasal decongestion.

7. Reasonable consumers, like Plaintiff, have suffered an ascertainable loss of money, measured by the difference between the price paid for a properly branded product that effectively treated nasal congestion and the lower market value of a product that was misbranded and/or failed to effectively treat nasal congestion. As a result of Defendants' illegal conduct, the purchase price of the PE Drugs was greater than their objective market value.

8. Accordingly, Plaintiff brings this action individually and on behalf of the Class defined below, comprised of all individuals similarly situated within the State of Washington, to redress the unlawful and deceptive practices employed by Defendants in connection with their labeling, marketing, and sale of PE Drugs.

9. Plaintiff seek redress for Defendants' reckless, knowing, and/or willful violations of Washington's Consumer Protection Act (RCW ch. 19.86, *et seq.* (herein referred to as "WCPA")

JURISDICTION AND VENUE

10. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§1332(d), because there is diversity of citizenship between members of the proposed Class and Defendants. Defendants are either incorporated and/or have their principal place of business outside the state in which Plaintiff and members of the proposed Class reside. Furthermore, there are more than 100 Class Members and the amount-in-controversy exceeds $5,000,000 exclusive of interest and costs.

11. This Court has personal jurisdiction over Defendants because Defendants are foreign corporations authorized to do business in Washington and registered with the Washington Secretary of State, and have sufficient minimum contacts with Washington or otherwise intentionally avail themselves of the laws and markets of Washington, through the promotion, sale, marketing and distribution of the Product in Washington, to render the exercise of jurisdiction by the Washington courts permissible.

12. Venue is proper in this District under 28 U.S.C. §1391(b) and (c) because Defendants' improper conduct alleged in this complaint occurred in and/or emanated from this judicial district, because Defendants have caused harm to Class Members residing in this district, and/or because Defendants are subject to personal jurisdiction in this district.

THE PARTIES

13. Plaintiff, JAMES CARRIGAN, is an individual, a resident of King County, and a member of the Class alleged herein, having purchased PE Drugs from Defendants during the Class Period.

14. Defendant JOHNSON & JOHNSON ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

15. Defendant THE PROCTER & GAMBLE COMPANY ("P&G") is an Ohio corporation with its principal place of business in Cincinnati, Ohio.

16. Defendant WALGREEN CO. is an Illinois corporation with its principal place of business in Deerfield, Illinois.

17. At all relevant times, Defendants engaged in the manufacturing, sale, and/or distribution of misbranded and ineffective PE Drugs in Washington and throughout the United States, and are responsible for the illegal label representations and/or conduct likely to cause

confusion complained of herein.

18. Defendants transacted and conducted business within the State of Washington that relates to the allegations in this Complaint, and derived substantial revenue from goods and products bought and used in the State of Washington (including but not limited to King County), including the PE Drugs at issue.

19. Defendants purposefully availed themselves of the privilege of conducting activities within the State of Washington, thus invoking the benefits and protections of its laws.

FACTUAL ALLEGATIONS

A. History of PE Drugs

20. Phenylephrine ("PE") is a specific alpha-1 adrenergic receptor agonist that works by temporarily constricting blood vessels. By contrast, pseudoephedrine ("PSE") is a relatively less selective agonist that acts on both alpha and beta-adrenergic receptors. The literature reports that PSE is more lipophilic than PE and thus is more accessible to the central nervous system by crossing the blood-brain barrier (Gheorghiev et al. 2018). The vasoconstriction effect of PSE is likely contributed to by an indirect action via release of norepinephrine in synaptic nerve terminals (Gorodetsky 2014).

21. The FM for OTC nasal decongestant drug products, issued in 1994, classified the PEH as a GRASE nasal decongestant when administered orally (immediate-release [IR] formulations) or intranasally (M012.80, previously 21 CFR 341.80). The PEB, an IR effervescent tablet for oral administration, was added to the monograph in 2006, based on pharmacokinetic (PK) data demonstrating that it has similar bioavailability to PEH.

22. The PE drugs at issue in this case fall within two categories:

a. Phenylephrine hydrochloride

b. Phenylephrine bitartrate

23. The Federal Register, dated August 23, 1994 on page 433861 under section III, first allowed Phenylephrine hydrochloride to be sold: "Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective and not misbranded. Specifically, the following ingredients are included in the final monograph as OTC oral nasal decongestants: Phenylephrine hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate."[3]

24. Subsequently, Phenylephrine bitartrate was included in the Federal Register on August 1, 2006 on page 833582: "The Food and Drug Administration (FDA) is issuing a final rule to amend the final monograph (FM) for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies) to add phenylephrine bitartrate (PEB), both individually and in combination drug products in an effervescent dosage form, as generally recognized as safe and effective (GRASE)."[4]

25. As a result of the market withdrawal and restrictions on the sale of other α-adrenergic agonists in the early and mid-2000s, Pfizer, Inc, introduced a replacement product (Sudafed-PE) that contained PE. Other manufacturers, including Defendants in this case, similarly followed suit by releasing products containing PE.

B. Questions Surrounding the Efficacy of PE Drugs

26. Phenylephrine is an over-the-counter (OTC) ingredient marketed in both single ingredient and combination products.[4] It has been available in the United States more than 75 years

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[3] Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Nasal Decongestant Drug Products, 59 Fed. Reg. 43386-01 (Aug. 23, 1994).

[4] Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products, 71 Fed. Reg. 43358-01 (Aug. 1, 2006).

and globally (e.g., Canada, Australia, UK).

27. PE has largely been approved for the temporary relief of nasal congestion due to the common cold, hay fever, or other respiratory allergies, or allergic rhinitis under the cough, cold, allergy, bronchodilator, and anti-asthmatic drug products monograph ("final monograph" or "CCABADP").

28. On May 1, 2006, two professors at the University of Florida published a letter questioning the effectiveness of PE for nasal congestion based upon the results of multiple double blind, placebo-controlled studies, that show PE was no more effective than placebo in reducing nasal airway resistance.[5] Moreover, the letter notes that the studies relied on by the FDA to approve PE were unpublished, manufacturer-sponsored studies conducted by commercial testing laboratories.

29. On February 1, 2007, those professors filed a Citizens Petition with the FDA concerning PE Drugs.[6]

30. Specifically, the Petition requested the dosage of oral phenylephrine (PE) be re-evaluated and that approval for use in children under twelve years old be withdrawn.[7] The Petition further stated that there was no data on the safety of PE in children under twelve years old.[8]

31. As a result of the 2007 Citizens Petition, the FDA's Nonprescription Drugs Advisory Committee met on December 14, 2007 and concluded that the products could continue

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[5] L. Hendeles and R. Hatton, *Oral phenylephrine: An ineffective replacement for pseudoephedrine?*, 118 J. ALLERGY AND CLINICAL IMMUNOLOGY 279 (2006), https://www.jacionline.org/article/S0091-6749(06)00633-6/fulltext.

[6] L. Hendeles, et al., Citizens Petition to U.S. Food and Drug Admin. (Feb. 1, 2007), https://downloads.regulations.gov/FDA-2007-P-0108-0005/attachment_1.pdf.

[7] *Id.* at 1-2.

[8] *Id.* at 2-3.

to be sold, but 9 of 12 of the committee members voted that new studies on response to higher doses were required.[9] Further, a member of the Division of Nonprescription Drug Products expressed a preference for subjective symptom scores over objective measurement of nasal airway resistance to support the use of PE for temporary relief of nasal congestion.[10]

32. Schering-Plough Pharmaceuticals responded to the recommendations of the Committee and the Division by conducting a multicenter, phase 2, parallel trial among 539 adults with seasonal allergic rhinitis. The results of the study revealed no significant differences between placebo and active treatment groups.[11]

33. Another manufacturer, McNeil Consumer Healthcare, conducted a pharmacokinetic, safety and cardiovascular tolerability study of PE. Similarly, this study revealed no difference in safety endpoints between placebo and 10, 20 and 30 mg of PE even though systemic exposure increased disproportionately with dose. According to the petitioners, "This is noteworthy since both the relief of congestion and systemic endpoints such as change in blood pressure and pulse are mediated by alpha adrenergic stimulation. The absence of a significant effect on the latter at the higher doses suggest that the concentrations reached are not sufficient to stimulate alpha adrenergic receptors."[12]

34. On November 4, 2015, the authors of the 2007 Citizen Petition filed an additional

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[9] U.S. Food and Drug Admin., Summary Minutes of the NDAC meeting (Dec. 14, 2007), avail. at https://wayback.archive-it.org/7993/20170403222236/https://www.fda.gov/ohrms/dockets/ac/07/minutes/ 2007-4335m1-Final.pdf. (last accessed Sep. 17, 2023).

[10] L. Hendeles and R. Hatton, Citizens Petition to U.S. Food and Drug Admin. (Nov. 4, 2015), avail. at https://truthinadvertising.org/wp-content/uploads/2023/02/Hatton-Hendeles-2015-Citizens-Petition-re-oral-phenylephrine.pdf, at 2.

[11] *Id.*

[12] *Id.* at 3.

Citizens Petition asking the FDA "to remove oral phenylephrine from the Final Monograph for OTC nasal decongestant products." Specifically, the petition asked the FDA to remove Phenylephrine and to remove phenylephrine bitartrate (PEB), "both individually and in combination drug products in an effervescent dosage form[.]"[13]

35. According to the 2015 Citizens Petition, "Two additional studies published in 2009 provide further evidence of the absence of a decongestant effect from the FDA-approved nonprescription dose of 10 mg. Horak et al conducted a 3-way crossover, placebo-controlled study of the nasal decongestant effect of single doses of PE 12 mg, pseudoephedrine 60 mg or placebo among 39 grass-sensitive adults exposed to grass pollen in the Vienna Challenge Chamber. PE was not significantly different from placebo in the mean change in subjective nasal congestion scores whereas pseudoephedrine, a positive control in the study, decreased congestion significantly greater than placebo and PE."[14]

36. The 2015 Citizens Petition was further supported by the American Academy of Allergy, Asthma & Immunology.[15]

37. On information and belief, at this time, each Defendant did not do additional testing and quality oversight of their respective PE Drugs to ascertain the true effectiveness for treating nasal congestion, or deliberately suppressed or avoid doing so. Had they done so and/or disclosed the results, the data would lead to the same inexorable conclusion reached on September 12, 2023 by an FDA Advisory Panel: PE is not effective for treating nasal congestion at all.

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[13] *Id.* at 1.

[14] *Id.* at 4.

[15] Am. Academy of Allergy, Asthma & Immunology, Statement of Support of Citizens Petition (May 4, 2022), avail. at https://college.acaai.org/wp-content/uploads/2022/05/oral-phenylephrine-final-statement-in-support-of-citizens-petition-05-4-22.pdf (last accessed Sep. 17, 2023).

C. The FDA Advisory Panel's Unanimous Vote

38. On September 12, 2023, the FDA Advisory Panel on the Division of Nonprescription Drugs recommended that PE Drugs not be sold due to lack of efficacy.[16]

39. In the FDA's Briefing Document regarding the hearing that took place on September 11-12, 2023, the FDA notes that it has been reviewing the clinical studies on the efficacy of PE since the 2007 Citizens Petition.[17]

40. The Advisory Panel concluded,

> In accordance with the effectiveness standard for determining that a category of over-the-counter (OTC) drugs is generally recognized as safe and effective that is set forth in 21 CFR § 330.10(a)(4)(ii), which defines effectiveness as: "a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed", we have now come to the initial conclusion that orally administered PE is not effective as a nasal decongestant at the monographed dosage (10 mg of PE hydrochloride every 4 hours) as well as at doses up to 40 mg (dosed every 4 hours).[18]

41. The Advisory Panel met for two days on September 11-12, 2023. During this meeting, FDA scientists presented the results of five studies conducted over the past two decades on the effectiveness of oral phenylephrine. All the studies concluded that the decongestant was no more effective than a placebo. The Advisory Panel further reevaluated the initial findings which supported PE Drugs' use and found that the results were inconsistent, did not meet modern study

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[16] U.S. Food and Drug Admin., Efficacy of Oral Phenylephrine as a Nasal Decongestant (Sep. 12, 2023), https://www.fda.gov/media/171915/download.

[17] *Id.*

[18] *Id.*

design standards and further that these studies may have data integrity issues:[19]

> "In conclusion, we do believe that the original studies were methodologically unsound and do not match today's standard. By contrast, we believe the new data are credible and do not provide evidence that oral phenylephrine is effective as a nasal decongestant," said Dr. Peter Starke, an FDA official who led the review of phenylephrine.[20]

42. At the conclusion of the meetings, members voted unanimously (16-0) that PE drugs were ineffective, paving the way for the drugs to be removed from the market.

43. Following this vote by the Advisory Panel, the FDA will now need to decide whether PE Drugs can still be sold and whether drugs should lose their designation as Generally Recognized as Safe and Effective (GRASE).

D. Misbranded Drugs Are Illegal to Sell

44. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

45. A drug is misbranded:

a. "If its labeling is false or misleading in any particular"[21];

b. "If any word, statement, or other information required … to appear on the label or labeling is not prominently placed thereon…in such terms as to

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[19] B. Lovelace, FDA panel says common over-the-counter decongestant doesn't work, NBC NEWS (Sep. 12, 2023), https://www.nbcnews.com/health/health-news/fda-panel-says-common-counter-decongestant-phneylephrine-doesnt-work-rcna104424 (last accessed Sep. 17. 2023).

[20] *Id.*

[21] 21 U.S.C. § 352(a)(1).

render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use"[22];

c. If the labeling does not contain, among other things, "the proportion of each active ingredient"[23];

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users"[24];

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein"[25]

f. "if it is an imitation of another drug"[26];

g. "if it is offered for sale under the name of another drug"[27];

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"[28];

i. If the drug is advertised incorrectly in any manner[29]; and/or

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[22] 21 U.S.C. § 352(c).

[23] 21 U.S.C. § 352(e)(1)(A)(ii).

[24] 21 U.S.C. § 352(f).

[25] 21 U.S.C. § 352(g).

[26] 21 U.S.C. § 352(i)(2).

[27] 21 U.S.C. § 352(i)(3).

[28] 21 U.S.C. § 352(j).

[29] 21 U.S.C. § 352(n).

j. If the drug's "packaging or labeling is in violation of an applicable regulation."[30]

46. The manufacture and sale of any misbranded drug is prohibited under federal law.[31]

47. The introduction into commerce of any misbranded drug is also prohibited.[32]

48. Similarly, the receipt in interstate commerce of any misbranded or misbranded drug is also unlawful.[33]

49. As articulated in this Complaint, Defendants' sale of PE Drugs that were not effective for treating the indications identified were misbranded in violation of the above-cited reasons.

50. Plaintiff' reference to federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on any Defendant, beyond what is already required of them under federal law.

i. Defendants Made False Statements in the Labeling

51. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"[34] and conform to requirements governing the appearance of the label.[35]

52. "Labeling" encompasses all written, printed or graphic material accompanying the

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[30] 21 U.S.C. § 352(p).

[31] 21 U.S.C. § 331(g).

[32] 21 U.S.C. § 331(a).

[33] 21 U.S.C. § 331(c).

[34] 21 C.F.R. § 201.5.

[35] 21 C.F.R. § 801.15.

drug or device,[36] and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

53. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[37]

54. Because the labels on Defendants' PE drugs indicate that PE can be used to treat nasal congestion, the subject drugs were misbranded.

55. It is unlawful to introduce a misbranded drug into interstate commerce.[38] Thus, the PE Drugs purchased and ingested by Plaintiff were unlawfully distributed and sold.

ii. Each Defendant's Unlawful Statements to Consumers

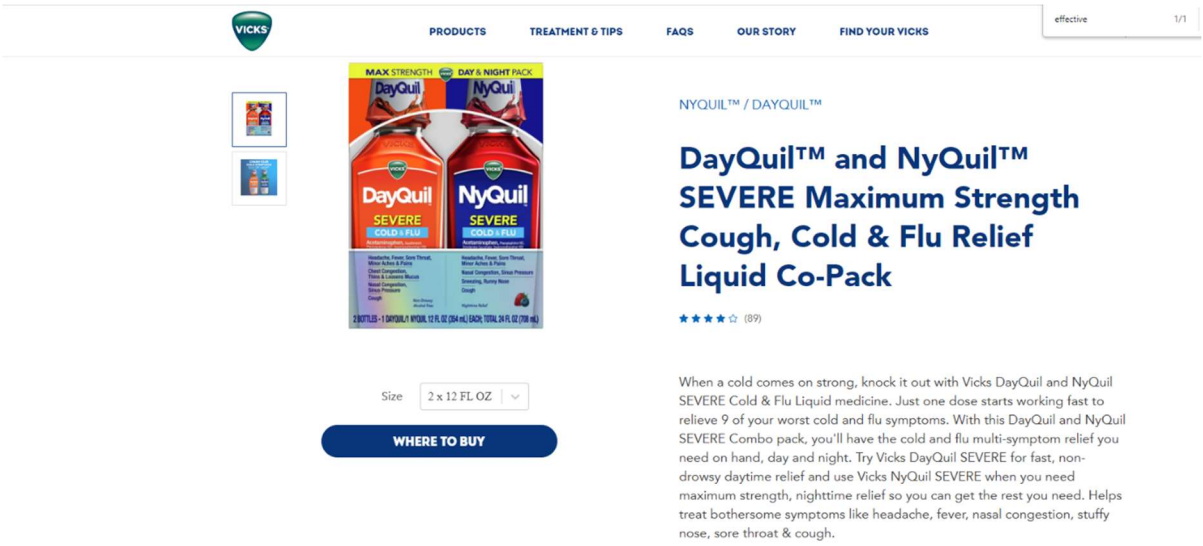
56. Each Defendant engaged in unlawful practices with respect to their representations and omissions to consumers regarding their PE Drugs.

57. P&G, for instance, touted its PE Drugs as effective for treating nasal congestion. Its website states:

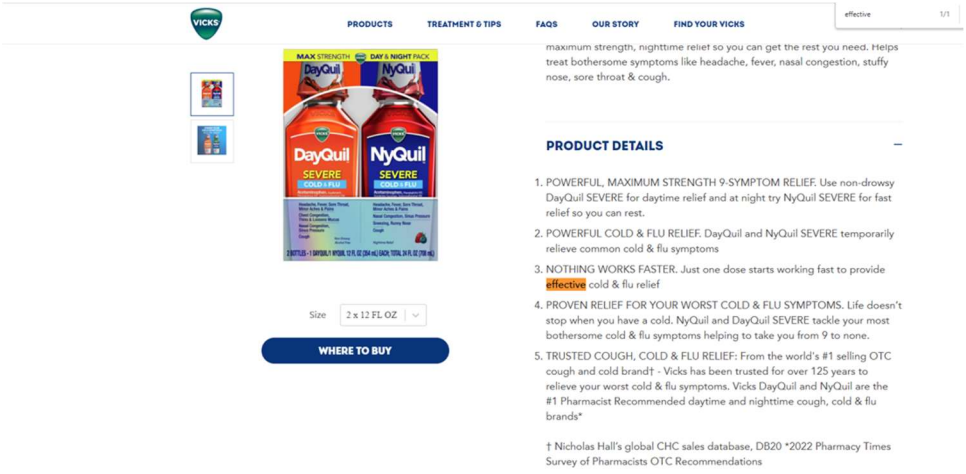
[36] *Id.* 65 Fed. Reg. 14286 (March 16, 2000).

[37] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).

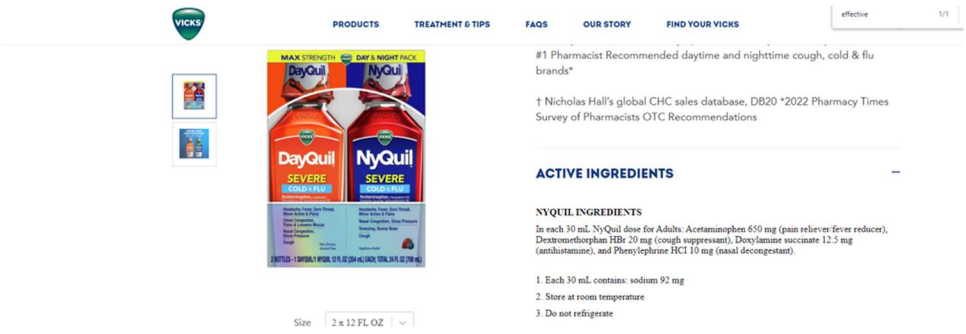
[38] 21 U.S.C. § 331(a).



58. P&G further emphasized its drugs' effectiveness (see highlighting below):



59. Each of P&G's PE Drugs contained PE as an advertised active ingredient supposedly effective at treating nasal congestion:



60. P&G's representations on its website, product packaging, product label, and other advertisements and promotions, were false, misleading, and/or likely to cause confusion or misunderstanding. Contrary to P&G's statements, and undisclosed by P&G, PE was not effective at all for treating nasal congestion. P&G knew, or should have known, this was the case.

61. Defendants J&J and Walgreens make similar claims in their marketing, websites,[39] and labeling (as exemplified below):

62. At all relevant times, each Defendant represented that their respective PE Drugs were effective for treating the indications identified (including nasal decongestion).

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[39] *See, e.g.,* https://www.walgreens.com/store/c/walgreens-severe-cold-&-flu-day-&-night-combo-caplets/ID=prod6286382-product (describing PE as "nasal decongestant" in PE Drug which is used to relief, *inter alia*, "nasal congestion") (last accessed Sep. 18, 2023); https://www.tylenol.com/products/tylenol-cold-flu-severe-caplets (describing Tylenol Cold + Flu as "[c]onvenient caplets to tackle your tough cold and flu symptoms by clearing congestion, quieting coughs and relieving head and body aches") (last accessed Sep. 18, 2023).

iii. Discovery of Defendants' Unlawful Acts and Practices

63. Plaintiff and Class Members' causes of action accrued on the date the FDA announced that PE was not effective at treating the indications identified in Defendants' PE Drug labeling and packaging, that is, September 12, 2023. This is the first date when Plaintiff and Class Members could have reasonably discovered Defendants' unlawful methods, acts, and/or practices as described herein.

64. Each Defendant affirmatively concealed from Plaintiff and other Class Members its unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of the ineffectiveness of their respective PE Drugs for treating the indications identified, and/or that such products were misbranded.

65. For instance, no Defendant revealed to the public that their PE Drugs were *not* effective at treating the indications identified, or that in fact PE was not effective at all to treat same (principally, nasal decongestion), despite reasons to believe the contrary due to their superior knowledge and position and the manufacturer or seller of their respective PE Drugs.

66. To the contrary, each Defendant continued to represent and warrant that its respective PE Drugs were effective for treating the indications identified, principally nasal decongestion.

67. Because of this, Plaintiff and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each Defendant's unlawful methods, acts, and/or practices as alleged herein.

CLASS ACTION ALLEGATIONS

68. Plaintiff bring this class action pursuant to Rules 23(a), 23(b)(2), and/or 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the following Class:

All persons in the State of Washington who purchased Defendants' PE Drugs for personal use and not for resale.

69. Specifically excluded from the proposed Class are Defendants, their officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or their officers and/or directors, or any of them. Also excluded from the proposed Class are the Court, the Court's immediate family and Court staff.

70. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint

71. Plaintiff meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

72. **Numerosity**: Membership in the Class is so numerous that separate joinder of each member is impracticable. The precise number of Class Members is unknown at this time but can be readily determined from Defendants' records. Plaintiff reasonably estimate that there are at least thousands of persons in the Class.

73. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class and Subclass Members and predominate over any questions affecting on individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

a. Whether each Defendant represented its PE Drugs as effective for treating the indications identified (including nasal decongestion);

b. Whether each Defendant's PE Drugs were effective for treating the indications identified (including nasal decongestion);

c. Whether the PE Drugs as represented by the Defendants are inherently worth more than the products actually received by Class Members;

d. Whether Defendants' violations of the WCPA were willful, reckless, and/or knowing; and

e. When Plaintiff' and Class Members' causes of action accrued.

74. **Typicality**: Plaintiff' claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

75. **Adequacy of Representation**: Plaintiff are committed to pursuing this action and has retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiff and their counsel will fairly and adequately protect the interests of Class Members. Plaintiff' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

76. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

77. **Superiority**: A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against each Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial

adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiff. Plaintiff' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

CLAIMS FOR RELIEF

78. Based on the foregoing allegations, Plaintiff' claims for relief include the following:

FIRST CAUSE OF ACTION

Violations of Washington's Consumer Protection Act (RCW ch. 19.86)

79. Each of the above allegations is incorporated herein.

80. Plaintiff brings this claim individually, and on behalf of the Class for violations of the Washington Consumer Protection Act ("WCPA") that provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." RCW § 19.86.020.

81. As the purpose of the WCPA is "to protect the public and foster fair and honest competition," the act is "liberally construed" to serve its beneficial purposes. RCW § 19.86.920.

82. The WCPA prohibits (a) an unfair or deceptive act or practice, (b) occurring in trade or commerce, (c) with a public interest impact, (d) that causes injury.

83. In the context of the WCPA, pleading and proof of an unfair or deceptive act or practice under RCW § 19.86.020 bears little resemblance to pleading and proof of common-law fraud. It can be predicated on an act or practice so designated by statute (i.e., a *per se* violation);

an act or practice that has the capacity to deceive substantial portions of the public; or an unfair or deceptive act or practice not regulated by statute but in violation of public interest. An act or practice can be unfair without being deceptive and still violate the WCPA.

84. Defendants' acts and practices described herein were unfair, had a capacity to deceive and injure a substantial portion of the public, and affect the public interest in numerous ways.

85. Defendants falsely marketed their respective PE Drugs as effective for treating indications identified on the label, most often nasal congestion.

86. However, Defendants' respective PE Drugs were not effective for treating all the indications identified and/or were misbranded..

87. Defendants' harmful conduct was willful as Defendant knew or should have known that the conduct complained of herein was deceptive and caused harm to the general public.

88. Plaintiff, and similarly situated reasonable consumers, have suffered an ascertainable loss of money, in purchasing PE Drugs from Defendants which had little to no value as they were not effective at reducing congestion, as falsely indicated on their labels and in their marketing materials.

89. The illegal conduct complained of herein was no isolated incident or one-time mistake; rather, it occurred over many years with respect to the PE Drugs sold by Defendants to Plaintiff and the Class, which caused likelihood of confusion or of misunderstanding as to the effectiveness of the Product.

90. Upon reasonable belief, Defendants continued to manufacture, market, and/or sell the PE Drugs without disclosing the ineffectiveness of their products.

91. Defendants' unfair and deceptive acts and practices impact the public interest in the

following ways, among others:

a) Defendants committed the acts and practices in the course of their everyday business;

b) The acts and practices are part of a pattern or generalized course of business.

c) Defendants committed the acts and practices repeatedly and continually both before and after Plaintiff's purchase of the PE Drugs;

d) There is a real and substantial potential for repetition of Defendants' conduct; and

e) All purchasers of the PE Drugs are affected or likely to be affected.

92. Further, Defendant's acts or practices as described herein violated a statute containing a specific legislative declaration of public interest or impact; namely, Washington's Food, Drug, and Cosmetic Act, RCW § 69.04, *et seq.* ("WFDCA"). The WFDCA was enacted to "safeguard…the public health and promotes the public welfare by protecting the consuming public from (a) potential injury by product use; (b) products that are adulterated; or (c) products that have been produced under unsanitary conditions, and the purchasing public from injury by merchandising deceit flowing from intrastate commerce in food, drugs, devices, and cosmetics; and (2) which is uniform, as provided in this chapter, with the federal food, drug, and cosmetic act; and with the federal trade commission act, to the extent it expressly outlaws the false advertisement of food, drugs, devices, and cosmetics[.]" RCW § 69.04.001. The violations of the FFDCA described herein, with respect to misbranding and adulteration, are also violations under the WFDCA. *See, e.g.,* RCW §§ 69.04.410-530 (adulteration and misbranding provisions).

93. Defendant conducted its acts and practices described herein in the course of trade or commerce.

94. Defendant's unfair and deceptive acts and practices proximately caused injury to

Plaintiff and the Class's property and proximately caused actual damages.

95. Plaintiff and the Class Members suffered an ascertainable loss caused by Defendants' misrepresentations and/or omissions because: Plaintiff and Class Members paid for PE Drugs that they reasonably expected and were labeled as effective in the treatment of nasal decongestion;

96. Plaintiff and Class Members would not have purchased the PE Drugs if Defendants had disclosed the ineffectiveness of the PE Drugs, and were thus damaged in the amount of the purchase price. Accordingly, Plaintiff seeks individually and on behalf of the Class: declaratory relief, injunctive relief to enjoin further violations of the WCPA, actual damages, statutory damages in the amount of $200.00, and attorneys' fees and costs.

97. Pursuant to RCW § 19.86.095, the attorney general of the State of Washington will be served with a copy of this pleading, and notice of same will be filed with this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the members of the Class defined herein, pray for judgment and relief on all Causes of Action as follows:

A. An order certifying that the action may be maintained as a Class Action, appointing Plaintiff as Class Representatives, and designating Plaintiff' counsel as counsel for the Class;

B. Injunctive relief against Defendants, directing Defendants to correct their practices in compliance with WCPA;

C. To pay actual and/or statutory damages of $200.00 damages to Plaintiff and all members of the Class;

D. Pre-judgment interest from the date of filing this suit;

E. Declaring that Defendants have committed the violations alleged herein;

F. Reasonable attorneys' fees;

G. Costs of this suit; and

H. Such other and further relief as the Court may deem necessary or appropriate.

JURY DEMAND AND NOTICE TO ATTORNEY GENERAL

Plaintiff and the Class, by and through undersigned counsel, hereby request a trial by jury as to all issues so triable. Further, upon filing this action, this Complaint shall be mailed to the Attorney General of the State of Washington, and proof of receipt of same shall be filed with this Court.

September 22, 2023

Respectfully submitted,

KU & MUSSMAN, P.A.

By: */s/ Brian Ku*

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